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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,555	12/23/2005	Scott Eugene Conner	2947.100/-004	2003

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EXAMINER	
KOSACK, JOSEPH R	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
07/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,555	CONNER ET AL.	
	Examiner	Art Unit	
	Joseph R. Kosack	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-7,10,19,22,31,34,43,49-52,55,64,67,76,79,88,92,94-96 and 140* is/are pending in the application.

4a) Of the above claim(s) *7,10,52,55,76 and 79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 92* is/are rejected.

7)☒ Claim(s) *4-6,19-22,31,34,43,49-51,64,67,88,94-96 and 140* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 3-7, 10, 19, 22, 31, 34, 43, 49-52, 55, 64, 67, 76, 79, 88, 92, 94-96, and 140 are pending in the instant application.

Amendments

The amendment filed on May 20, 2008 has been acknowledged and has been entered into the application file.

Election/Restrictions

Applicant's election without traverse of a modified Group IV (where X is attached at the 5 position of the indole ring instead of the 2 position) along with a single compound if the group is not acceptable, in the reply filed on April 21, 2008 is acknowledged. According to the single compound election, the carbon between the N and the O of the oxazole ring is attached to R2.

Claims 7, 10, 52, 55, 76, and 79 are withdrawn from further consideration in full and claims 3-6, 19-22, 31, 34, 43, 49-51, 64, 67, 88, 92, 94-96, and 140 are withdrawn from further consideration in part by the Examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Priority

The claim to priority as a 371 filing of PCT/US03/41698 filed on December 31, 2003, which claims benefit of 60/438,541 filed on January 6, 2003 has been granted in the instant application.

Information Disclosure Statement

The Information Disclosure Statement filed on July 6, 2005 has been considered by the Examiner.

Claim Objections

Claims 3-6, 19-22, 31, 34, 43, 49-51, 64, 67, 88, 92, 94-96, and 140 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified supra.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 92 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating type II diabetes, Syndrome X, and atherosclerosis, does not reasonably provide enablement for treating all conditions modulated by PPAR receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,

7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention is the treatment of any disease modulated by PPAR receptors.

The State of the Prior Art and the Predictability or Lack Thereof in the Art

The state of the prior art is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The instant claimed invention is highly unpredictable as discussed below:
It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

The Applicant has stated in the background of the invention on page 1 of the specification that there are at least three types of PPARs (NUC1 and PPAR-delta are the same receptor). Applicant further states that three of them have been implicated in diabetes mellitus, cardiovascular disease, obesity, Syndrome X, and gastrointestinal disease. Specifically, PPARs have been linked by various people to type II diabetes, obesity, atherosclerosis, inflammatory bowel disease, and Syndrome X. Treating

atherosclerosis is not enough to treat the wide array of conditions covered by the cardiovascular disease. The same can be said about inflammatory bowel disease and gastrointestinal disease. For small molecules in the pharmaceutical arts, in vitro testing to show binding affinity may be sufficient for enablement only when there is a clear path from the action performed on the target receptor or protein to the disease desired to be treated. The claim is drawn to diseases "modulated" by PPARs. One of skill in the art would need to know whether the compounds are agonists or antagonists in order to determine what conditions may be treated by the compounds.

Hence, in the absence of a showing of correlation between all diseases claimed as capable of treatment or prevention by administering a PPAR interacting compound, one of skill in the art is unable to fully predict possible results from the administration of the compound due to the unpredictability of the claimed compounds to treat the broad class of diseases claimed.

The Amount of Direction or Guidance Present and the Presence or Absence of Working Examples

The specification teaches that the compounds that are useful generally have an IC_{50} of less than 100 nM and teaches several prophetic animal models.

The Breadth of the Claims

The breadth of the claims is the treatment of any disease modulated by a PPAR.

The Quantity of Experimentation Needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine which other diseases, if any, can be treated with the

compounds of the instant invention, dosages, the method of drug delivery, and any potential combination therapies.

The Level of Skill in the Art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Thus, the specification fails to provide sufficient support of the broad use of the claimed compounds to treat any disease modulated by PPAR. As a result, necessitating one of skill to perform an exhaustive search for which diseases can be treated the claimed compounds in order to practice the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

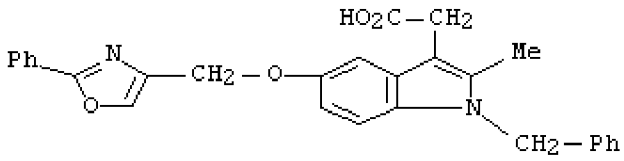
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Musser et al. (USPN 5,420,289).

Musser et al. teach the compound



which reads on the claims when X is O attached at the 5 position of the indole ring system, U is CH_2, T1 is oxazol-4-yl, R2-R33 is 2-phenyl, Z12 is attached at the 1 position and is benzyl, Y-E is attached at the 3 position and is CH_2-COOH, and R9 is attached at the 2 position and is methyl. See column 36, lines 12-23, Example 71.

Conclusion

Claims 3 and 92 are rejected. Claims 3-6, 19-22, 31, 34, 43, 49-51, 64, 67, 88, 92, 94-96, and 140 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/REI-TSANG SHIAO /
Primary Examiner, Art Unit 1626

/Joseph R Kosack/
Examiner, Art Unit 1626